K031095

JUN 2 0 2003

SUMMARY OF SAFETY AND EFFECTIVENESS

(As required by 21 CFR 807.92)

1. General Information

Classification:	Class II Magnetic Resonance Imaging (MRI) Accessory
Common/Usual Name:	Magnetic Resonance Imaging (MRI) Coil
Proprietary Name:	SENSE Body Coil
Establishment Registration:	Philips Medical Systems MR PMG Cleveland 595 Miner Road Highland Heights, Ohio 44143 Contact: Duane C. Praschan Phone Number: (440) 483-3000 FDA Owner Number: #1217116 FDA Registration Number: #1525965
Performance Standards:	Not Applicable.

2. Intended Uses

The SENSE Body Coil does not change the intended use of the Philips 1.5T Infinion system.

The 1.5T Infinion system is intended for use as a NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon NMR parameters (proton density, flow velocity, spin-lattice relaxation time T1, spin-spin relaxation time T2) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

The SENSE Body Coil is indicated for use in the following anatomic regions and with the designated nuclei:

Anatomic Regions:	Abdominal, pelvic and thoracic.
Nuclei Excited:	Hydrogen.

3. Device Description

The SENSE Body Coil is enclosed in a flexible, water-resistant fabric housing and is secured to the patient with Velcro straps. This receive-only coil is designed to give improved signal-to-noise, image resolution and image acquisition time over that of the standard body coil.

4. Safety and Effectiveness

The Philips SENSE Body Coil is substantially equivalent to the Philips Phased Array Flexible Cardiac Coil (K984588) in safety and effectiveness. The following chart has been compiled to demonstrate this equivalence.

Parameter	SENSE Body Coil	Predicate Device: Phased Array Flexible Cardiac Coil (K984588)
Compatible MRI Systems	Same.	Philips 1.5T Infinion Systems
Mode of Operation	Same.	Receive-Only
Antenna Configuration	Two anterior loops and two posterior loops.	Co-rotating saddle coils and loops
Tuning/Impedance Matching	Same.	Fixed tuning and matching. Factory set.
Method of Decoupling	Same.	Active PIN diode decoupling
Coil Enclosure	Same.	Flame rated foam and fabric
Number of Receive Channels	Same.	Four
Intended Use	Same.	The 1.5T Infinion system is intended for use as a NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon NMR parameters (proton density, flow velocity, spin-lattice relaxation time T1, spin-spin relaxation time T2) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

Parameter	SENSE Body Coil	Predicate Device: Phased Array Flexible Cardiac Coil (K984588)
Indications for Use	The Flexible Cardiac Coil is indicated for use in the following anatomic regions and with the designated nuclei: *Anatomic Regions*: Abdominal, pelvic and thoracic regions. *Nuclei Excited*: Hydrogen	The Flexible Cardiac Coil is indicated for use in the following anatomic regions and with the designated nuclei: *Anatomic Regions*: Heart and associated structures in the thoracic region. *Nuclei Excited*: Hydrogen.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2003

Mr. Duane C. Praschan
Manager, Regulatory Affairs
Philips Medical Systems (Cleveland) Inc.
595 Miner Road
Cleveland OH 44143

Re: K031095
Trade/Device Name: SENSE Body Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic imaging
Regulatory Class: II
Product Code: 90 MOS
Dated: April 4, 2003
Received: April 30, 2003

Dear Mr. Praschan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K 031095

Device Name: SENSE Body Coil

Indications for Use:

Intended Use

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The 1.5T Infinion system is intended for use as a NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon NMR parameters (proton density, flow velocity, spin-lattice relaxation time T1, spin-spin relaxation time T2) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

Indications for Use

The SENSE Body Coil is indicated for use in the following anatomic regions and with the designated nuclei:

Anatomic Regions: Abdominal, pelvic and thoracic regions

Nuclei Excited: Hydrogen.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031095

Prescription Use √ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)